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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,263	07/27/2001	Jing Wu	002010-593	7971

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EXAMINER

KIFLE, BRUCK

ART UNIT PAPER NUMBER

1624

DATE MAILED: 06/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,263

Applicant(s)

Wu et al.

Examiner

Bruck Kifle, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/11/02 and 4/16/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-117 is/are pending in the application.
- 4a) Of the above, claim(s) 99-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 91-98 and 113-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

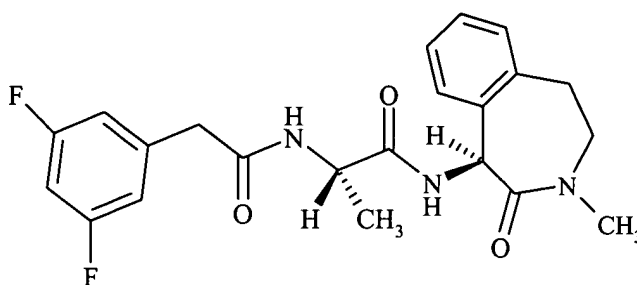
Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 & 1 6) ☐ Other:

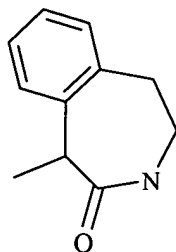
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Election/Restriction

Applicant's election without traverse of the compound depicted below in Paper No. 11 is acknowledged.



The search was conducted to embrace compounds wherein W, together with -
 $C(H)_pC(=X)$, and Q forms the ring system:



Claims 99-112 along with subject matter not embraced by this ring system of the remaining claims are withdrawn from consideration as being drawn to non-elected subject matter.

Improper Markush Rejection

Claims 91-98 and 113-117 are rejected under a judicially created doctrine as being drawn to an improper Markush group, that is, the claims lack unity of invention. The variables R^1 and the ring formed by W, together with $-C(H)_pC(=X)$, and Q are defined in such a way that they keep changing the core of the compound that determines the classification. By changing these

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values, several patentably distinct and independent compounds are claimed. In order to have unity of invention the compounds must have "a community of chemical or physical characteristics" which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification" In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The structural formula IA and IB do not have a significant structural feature that is shared by all of its alternatives which is inventive. The structural formula IA and IB only have the -NH-C(O)-CH(R²)-NH-C(O) fragment as common. Compounds embraced by formula IA and IB are so diverse in nature that a prior art anticipating a claim with respect to one member under 35 USC 102 would not render obvious the same claim under 35 USC 103. This is evidentiary of patentably distinct and independent inventions.

Limiting the claims to compounds wherein W, together with -C(H)_pC(=X), and Q form the elected ring system (the benzoazepin-2-one ring) would overcome this rejection.

Claim Rejections - 35 USC § 112

Claim 94 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 94 improperly depends on claims 91-93. Claim 94 is drawn to a pharmaceutical composition while claims 91-93 are drawn to a method of use each.

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Claims 92, 96, 98 and 113-117 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for preventing the onset of AD in humans.

In evaluating the enablement question, several factors are to be considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention: These claims are drawn in part to preventing the onset of AD

2) The state of the prior art: There are no known compounds which have been demonstrated to prevent Alzheimer's disease.

3) The predictability or lack thereof in the art: It is presumed in the prevention of the diseases and/or disorders that there is a way of identifying those people who may develop AD. There is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with AD.

4) The amount of direction or guidance present and 5) the presence or absence of working examples: There are no doses present to direct one to protect a human host from AD and there is no data present for the prevention of AD.

6) The breadth of the claims: The claims are drawn to a disorder whose prevention is unknown.

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7) The quantity of experimentation need would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan for the many reasons stated above. Getting agents to be effective against AD has proven extremely difficult. Despite extraordinary efforts with a variety of agents in this area, only two pharmaceuticals have been made to treat AD, both acetylcholinesterase antagonists, a property that these compounds are not disclosed to have. No one has been able to figure out how to get inhibitors of β -amyloid peptide release and/or its synthesis to be effective to prevent the onset of AD, which is evidence of the low skill level in this art relative to the difficulty of the task.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

Provisos

There are provisos in the claims that exclude compounds embraced by the claims. If these provisos are present to avoid prior art, applicants are urgently requested to point out these references to the examiner because of their importance in the examination of the claims.

The search revealed that the compound of RN 425386-60-3 is disclosed in WO 2002/040,051 (US 60/249,656) which is Applicant's pending application. Also, application 09/338,180 contains compounds instantly claimed. Applicants are required to maintain a clear line of demarcation between the applications. See MPEP § 822.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

June 7, 2002

A handwritten signature in black ink, appearing to read 'Bruck Kifle', with a stylized flourish at the end.

Bruck Kifle
Primary Examiner
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